

REMARKS

Following amendment, claims 1, 2, and 4-15 will be pending in this application. Claims 1 and 5-7 are amended herein, and new claims 12-15 are added. Support for the amendments and new claims can be found throughout the specification and claims as filed, e.g., at page 8, lines 1-24, and Figure 2.

Applicants acknowledge and thank the Examiner for the withdrawal of the rejections for alleged anticipation and obviousness. Applicants address the remaining rejections below.

35 USC § 112, first paragraph

Claims 1, 2, and 4-11 were rejected as allegedly failing to comply with the written description requirement. The Office action states (at pages 3-4):

The lack description on the terms “low temperature” and “about”, and the lack of representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention. [Informal English in original].

Applicants do not concede that the claims fail to comply with the written description requirement. However, applicants have amended the claims, solely to further prosecution. Applicants have amended claim 1 to recite “1 °C to 7 °C” instead of “low temperature” and have deleted the term “about” in claims 5-7.

The test of whether the written description is satisfied is whether, as of the filing date, the applicant conveyed with reasonable clarity to those skilled in the art that she was in possession of the subject matter of the claims. *See, Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). As the Office action points out (at page 3), the specification provides specific examples of the stabilization of IgM at temperatures of 1 °C, 4 °C, and 7 °C (see Example 2 and Figure 2). Based on this disclosure, one skilled in the art would recognize that Applicants were in possession of the claimed methods of stabilizing IgM at the entire range of temperatures from 1 °C to 7 °C. *See, Vas-Cath*, 935 F.2d at 1566 (“ranges found in applicant's claims need not correspond exactly to those disclosed in [the specification]; issue is whether one skilled in the art could derive the claimed ranges from the [] disclosure.”).

It is clear the Applicants disclosed the general concept of stabilization at low temperatures (see, e.g., page 3, lines 20-21, and page 4, lines 7-14), so certainly did not communicate that the method was limited to the three precise temperatures tested (1 °C, 4 °C, and 7 °C). One of ordinary skill would understand that, if the method works to stabilize IgM at 1 °C, 4 °C, and 7 °C, then it would also be expected to work at any temperature within the range of 1 °C to 7 °C. Therefore, Applicants request reconsideration and withdrawal of the rejection under section 112, first paragraph.

35 USC § 112, second paragraph

Claims 1, 2, and 4-11 were rejected as allegedly indefinite “because of the use of the term ‘low temperature’ or ‘about’” (Office action at page 4). Applicants do not concede that the claims are indefinite. However, as noted above, Applicants have amended the claims such that they no longer recite “low temperature” or “about,” solely to further prosecution. Therefore, Applicants request withdrawal of the rejection under section 112, second paragraph.

CONCLUSION

Applicants submit that all claims are in condition for allowance, which action is requested. This response is being submitted along with a Petition for Extension of Time and the required fee. Please apply any other charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 14875-158US1.

Respectfully submitted,

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